

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Joel S. Greenberger et al.



Title: PROTECTION FROM
IONIZING IRRADIATION OR
CHEMOTHERAPEUTIC
DRUG DAMAGE IN VIVO
GENE THERAPY

Appl. No.: 08/907,041

Appl. Filing Date: 08/06/1997

Examiner: S. Chen

Art Unit: 1633

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REQUEST FOR CONTINUED EXAMINATION (RCE)
TRANSMITTAL

Commissioner for Patents
Box RCE
Washington, D.C. 20231

Sir:

This is a Request for Continued Examination (RCE) under 37 C.F.R. § 1.114 of the above-identified application. This RCE and the enclosed items listed below are being filed prior to the earliest of: (1) payment of the issue fee (unless a petition under 37 C.F.R. § 1.313 is granted); (2) abandonment of the application; or (3) the filing of a notice of appeal to the U.S. Court of Appeals for the Federal Circuit under 35 U.S.C. §141, or the commencement of a civil action under 35 U.S.C. §145 or §146 (unless the appeal or civil action is terminated).

1. Submission required under 37 C.F.R. §1.114: (check items that apply)

a. Previously submitted:

- ☐ Please enter and consider the amendment/reply previously filed on ____.
- ☐ Please consider the Affidavit(s)/Declaration(s) previously filed on ____ but not considered.
- ☐ Please consider the arguments in the Appeal Brief or Reply Brief under 37 C.F.R. § 1.116 previously filed on ____.
- ☐ Other ____.

b. Enclosed are:

- ☒ Amendment/Reply.
- ☐ Affidavit(s)/Declaration(s).
- ☐ Information Disclosure Statement.
- ☐ Form PTO-1449 with copies of ___ listed reference(s).
- ☒ Petition for Extension of Time.

Miscellaneous:

- ☐ Suspension of action of the above-identified application is requested under 37 C.F.R. § 1.103(c) for a period of ___ months.

The filing fee is calculated below:

	Claims as Amended	Previously Paid For	Extra Claims Present	Rate	Fee Totals
RCE Fee 1.17(e)				\$740.00	\$740.00
Total Claims:	31	31	0	x \$18.00	= \$0.00
Independents:	2	3	0	x \$84.00	= \$0.00
First presentation of any Multiple Dependent Claims:				+ \$280.00	= \$0.00
CLAIMS FEE TOTAL:					= \$740.00

- ☒ Applicant hereby petitions for an extension of time under 37 C.F.R. § 1.136(a) for the total number of months checked below:

<input type="checkbox"/>	Extension for response filed within the first month:	\$110.00	\$0.00
<input type="checkbox"/>	Extension for response filed within the second month:	\$400.00	\$0.00
<input type="checkbox"/>	Extension for response filed within the third month:	\$920.00	\$0.00
<input type="checkbox"/>	Extension for response filed within the fourth month:	\$1,440.00	\$0.00
<input checked="" type="checkbox"/>	Extension for response filed within the fifth month:	\$1,960.00	\$1,960.00
EXTENSION FEE TOTAL:			\$1,960.00
CLAIMS AND EXTENSION FEE TOTAL:			\$2,700.00
<input checked="" type="checkbox"/>	Small Entity Fees Apply (subtract ½ of above):		\$1,350.00
<input type="checkbox"/>	Suspension of action requested under 37 C.F.R. § 1.103(c)		\$0.00
TOTAL FEE:			\$1,350.00

☒ A check in the amount of \$1,350.00 to cover the filing fee is enclosed.

☒ The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Please direct all correspondence to the undersigned attorney or agent at the address indicated below.

Date March 20, 2002

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Respectfully submitted,

Michael M. Bent
By Reg No. 34,717 *for*

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No. 076333/0108

In re patent application of

Joel S. Greenberger.

Filed: August 6, 1997

Serial No.: 08/907,041

Title: PROTECTION FROM IONIZING IRRADIATION OR CHEMOTHERAPEUTIC
DRUG DAMAGE BY *IN VIVO* GENE THERAPY



Group Art Unit: 1633

Examiner: S. Chen

SUBMISSION TO ACCOMPANY REQUEST FOR CONTINUED EXAMINATION

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

Applicants are filing a request for continued examination in this case, in order to provide evidence relating to the rejection under the first paragraph of Section 112 for lack of enablement. Examiner Chen has taken the position that the specification fails to enable methods that use vectors other than adenovirus. The examiner also states that the specification does not disclose any data demonstrating that proteins other than gamma glutamyl transpeptidase, MnSOD and metallothionein work. Finally, the examiner improperly requires data demonstrating successful expression *in vivo*.

Applicants now forward evidence on each of these points, in the form of articles submitted for publication and/or abstracts of material presented at scientific meetings by the inventor. The evidence includes:

(1) An abstract presented at the 43rd ASH Annual Meeting, which reports that the overexpression of MnSOD, delivered via herpes simplex virus (HSV), protects against murine intestinal damage induced by total body irradiation. The abstract demonstrates both (i) a vector other than adenovirus, and (ii) *in vivo* data showing successful expression and protection.

(2) An abstract submitted to the American Society of Gene Therapy, which reports on HSV/MnSOD expression in human hematopoietic cells, which again demonstrates a vector other than adenovirus.

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(3) A manuscript in press in *Radiation Research* which reports the use of both the MnSOD and Bcl-xl transgene in irradiation protection *in vitro*, and thus shows a gene other than gamma glutamyl transpeptidase, MnSOD and metallothionein.

(4) A manuscript in press in *Blood and Bone Marrow Transplantation*, demonstrating endothelial cell localization of MnSOD plasmid liposomes using an HA-epitope tagged MnSOD, which again demonstrates both (i) a vector other than adenovirus, and (ii) *in vivo* data showing successful expression and protection.

(5) An abstract presented at AACR in 2002, demonstrating successful expression and protection *in vitro* for another gene, a Cu/ZnSOD transgene.

The presently submitted evidence, along with data previously presented in Rule 132 declarations by Dr. Joel Greenberger and Dr. Michael Lotze, clearly support applicant's presumptively accurate disclosure that the present invention is supported across the full scope of that which is claimed. Reconsideration of the rejection under Section 112 is requested. Applicant plans to submit a terminal disclaimer to respond to the obviousness-type double patenting rejection in due course.

In view of the foregoing amendments and remarks, it is believed that all claims are in condition for allowance. Reconsideration of all rejections and a notice of allowance are respectfully requested. Should there be any questions regarding this application, the examiner is invited to contact the undersigned attorney at the phone number listed below.

March 20, 2002

Date

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5109
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Respectfully submitted,

Michael M. Hinkley

Reg No. 34,717

Barbara A. McDowell

Registration No. 31,640 *for*